# This Page Is Inserted by IFW Operations and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

## IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents will not correct images, please do not report the images to the Image Problem Mailbox.

#### **REMARKS**

The August 12, 2003 Office Action (paper # 14) and the references cited therein have been carefully considered. In view of the amendments presented herewith, and based on the following remarks, Applicant submits that the instant application is in condition for allowance.

#### Claim Rejections

Claim 32 was rejected under 35 U.S.C. § 112 as being indefinite. Claims 1, 6-8, 20-26, and 28-31 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,330,486 ("Wilk '486"). In addition, claims 9 and 27 were rejected under 35 U.S.C. 103(a) as being obvious over Wilk '486 in view of U.S. Patent No. 5,314,436 ("Wilk '436"). Claims 10-19 were rejected 35 U.S.C. 103(a) as being obvious over Wilk '486 in view of U.S. Patent No. 6,119,913 ("Adams et al"). Lastly, claim 32 was rejected as being obvious over Wilk '486 in view of U.S. Patent No. 5,782,396 ("Mastri et al"). Applicant has considered each of the claim rejections. For the reasons stated below, Applicant believes that all of the claim rejections are traversed and that the application is in condition for allowance.

### Claim Rejections - 35 U.S.C. § 112

The Examiner rejected claim 32 as lacking proper antecedent basis. Applicant has amended claim 32 to effect a suitable editorial revision.

#### Claim Rejections - 35 U.S.C. § 102

The Examiner concluded that Wilk '486 anticipates the surgical device as recited in Applicant's Claim 1. Applicant has amended Claim 1 to include a quick-connect fitting for directly coupling the first surgical instrument to the distal free end of the hollow shaft to enable the first surgical instrument to be connected with the first connector of the first rotatable drive shaft.

The Wilk '486 patent does not teach or disclose a quick-connect fitting for directly coupling the first surgical instrument to the distal free end of the hollow shaft. Instead, Wilk

'486 discloses a two-piece stapling instrument, with one half of the instrument, a stapling member, connected to the distal end of a shaft or mandrel. The half instrument provided by the stapling member can not be reasonably interpreted to constitute a quick-connect fitting. The only connector referred to in Wilk '486 is a "screw connector" which is not shown in the patent. (Col. 14, lines 18-26). The screw connector must be ejected from the stapling member by manual rotation of the mandrel. The structure that facilitates this operable connection is not disclosed. Assuming that Wilk '486 contains an adequate disclosure of the screw connector, a screw connector that requires manual rotation from a mandrel can not be reasonably interpreted to constitute a quick-connect fitting.

The quick-connect fitting, as recited in claim 1, offers structural and functional advantages not realized by the device in Wilk '486. For example, the quick-connect fitting permits the hollow shaft to be used with multiple surgical instruments. In addition, since the distal free end of the hollow shaft is not permanently attached to a stapler, the shaft can enter the body through natural passages, such as the mouth or rectum, with minimal trauma to the body. (See, e.g., Applicant's Specification, p. 43, lines 16-19.) These features and advantages are not taught in Wilk '486. Therefore, Applicant respectfully submits that amended Claim 1 is not anticipated by Wilk '486 and therefore should be allowed.

Claims 6-8 are dependent on amended Claim 1 and incorporate all the features of amended Claim 1. Therefore, Claims 6-8 are distinguishable over Wilk '486 for at least the same reasons that Claim 1 is distinguishable.

Next, the Examiner concluded that Wilk '486 anticipates the method recited in Applicant's Claim 20. Applicant has amended Claim 20 to recite the step of "inserting a hollow shaft having a distal free end and a shaft diameter into the body via a first orifice without any instrument supported on the distal free end, the hollow shaft containing a drive shaft rotatably disposed therein". Wilk '486 does not teach the step of inserting a hollow shaft having a distal free end and a shaft diameter into the body via a first orifice without any

instrument supported on the distal free end. Instead, Wilk '486 discloses a two-piece stapling instrument, with one half of the instrument, a stapling member, projecting from the distal end of a shaft or mandrel. The stapling member is attached to the distal end of the shaft, such that the shaft must be inserted into the body with the stapling member. (See, e.g., Figs. 7-8, 10). Therefore, the method recited in amended Claim 20 is not anticipated by Wilk '486. Indeed, Wilk '486 teaches the use of a half instrument mounted on a shaft; this is directly contrary to the claim language of independent claim 20.

Claims 21-26 and 28-31 are dependent on amended Claim 20 and therefore incorporate all the features recited in Claim 20. Therefore, Claims 21-26 and 28-31 are distinguishable from Wilk '486 for at least the same reasons that Claim 20 is distinguishable from Wilk '486. Therefore, Applicant believes that Claims 21-26 and 28-31 are in allowable form.

#### Claim Rejections - 35 U.S.C. § 103

The Examiner concluded that Claims 9 and 27 are obvious over Wilk '486 in view of Wilk '436. Claim 9 is dependent on amended Claim 1 and therefore incorporates all the features recited in amended Claim 1. In addition, Claim 27 is dependent on amended Claim 20 and therefore incorporates all the features recited in amended Claim 20. Therefore, Claims 9 and 27 recite a device or method involving a quick-connect fitting or coupling for coupling the hollow shaft with the surgical instrument after the hollow shaft and surgical instrument are inserted into the body. As discussed above, the Wilk '486 patent does not teach or disclose a quick-connect fitting or coupling for directly coupling the first surgical instrument to the distal free end of the hollow shaft after the shaft and instrument are inserted in the body. Instead, Wilk '486 discloses a two-piece stapling instrument, with one half of the instrument, a stapling member, being attached to the distal end of a shaft prior to insertion of the shaft into the body. Wilk '436 teaches a shaft that connects with a staple loading unit, but the shaft and stapler part are configured to connect with one another prior to insertion into the

patient. Therefore, the deficiency in Wilk '486 is not addressed by viewing Wilk '486 in combination with Wilk '436. As a result, the claimed device and method in Claims 9 and 27 are not taught or suggested by combining Wilk '486 with Wilk '436.

The Examiner concluded that Claims 10-19 are obvious over Wilk '486 in view of Adams et al. Claims 10-19 are dependent on amended Claim 1 and incorporate all the elements of amended Claim 1, including a quick-connect fitting for directly coupling a first surgical instrument to the distal free end of a hollow shaft, wherein the quick-connect fitting is configured to be coupled with the first surgical instrument after the hollow shaft is inserted into the body via a first orifice and after the first surgical instrument is inserted into the body via a second orifice. As stated above, Wilk '486 does not teach a quick-connect fitting for coupling a first surgical instrument with the distal free end of a hollow shaft after the two are inserted into the body. Instead, Wilk '486 teaches a mandrel that is connected with one part of a stapling device prior to insertion into the body. Adams et al also fails to teach or suggest a quick-connect fitting for coupling a first surgical instrument with the distal free end of a hollow shaft after the two are inserted into the body. Adams et al teaches an endoscope that removably connects with a stapling head, but there is no teaching or suggestion that the endoscope and stapling head are configured for connection after insertion into the body. In fact, some of the embodiments suggest that the endoscope and stapling head are intended to be connected prior to insertion into the body. For example, the embodiment shown in Fig. 15 requires that the user press the endoscope and stapling head together, and subsequently twist a threaded collar ring onto the stapling head (col. 10, lines 25-29). These actions are more likely carried out outside the body, and there is no suggestion that the connection could be made while the components are in the body. Therefore, the deficiency in Wilk '486 is not addressed by viewing Wilk '486 in combination with Adams et al. As a result, Claims 10-19 are not obvious over Wilk '486 in view of Wilk '436. Claims 11 and 15 were amended solely to bring those claims into conformity with amended Claim 1, and are not being amended to

overcome any specific rejection by the Examiner.

The Examiner concluded that Claim 32 was obvious over Wilk '486 in view of Mastri et al. Claim 32 is dependent on amended Claim 1 and incorporates all the features recited in amended Claim 1, including a quick-connect fitting for directly coupling a first surgical instrument to the distal free end of a hollow shaft, wherein the quick-connect fitting is configured to couple the first surgical instrument with the hollow shaft after the hollow shaft is inserted into the body via a first orifice and after the first surgical instrument is inserted into the body via a second orifice. As stated above, Wilk '486 does not teach a quick-connect fitting for coupling a first surgical instrument with the distal free end of a hollow shaft after the two are inserted into the body. Wilk '486 only discloses a mandrel connected to one part of a stapling device prior to insertion into the body, with no suggestion that the mandrel and stapler part are connected after insertion into the body. Similarly, Mastri et al does not teach or suggest a quick-connect fitting for coupling a first surgical instrument with the distal free end of a hollow shaft after the two are inserted into the body. Instead, Mastri et al teaches a hollow shaft or body that detachably connects with a staple loading unit prior to inserting the loading unit in the body. Therefore, the deficiency in Wilk '486 is not addressed by viewing Wilk '486 in combination with Mastri et al. As a result, Claim 32 is not obvious over Wilk '486 in view of Mastri et al.

#### New Claims

Applicant has added new Claims 33-41. Claims 33 and 34 recite a device and method involving a quick-connect fitting projecting from the distal free end of a hollow shaft, said quick-connect fitting having a fitting diameter substantially equal to the hollow shaft diameter so that the hollow shaft and quick-connect fitting form a substantially uniform diameter which facilitates easy passage and maneuvering of the hollow shaft and quick-connect fitting into the body. Claims 35-38 recite a device comprising a power console, a flexible hollow shaft, a first surgical instrument, a rotatable drive shaft disposed in the flexible hollow shaft, and a steering

cable disposed in the flexible hollow shaft. Claims 39-41 are directed to the device of Claim 1,

wherein the quick-connect fitting is attachable to the first surgical instrument, to the hollow

shaft, or both. None of the references cited by the Examiner teach or suggest the subject

matter in Claim 33-41. Moreover, Claims 33-41 are supported in the Applicant's specification

as originally filed and do not present new matter. As a result, Claims 33-41 are believed to be

allowable.

In light of the foregoing amendments and new claims, the Applicant believes that the

application is in a condition for allowance. The Examiner is encouraged to contact the

Applicant's undersigned attorney if the Examiner believes that issues remain regarding the

allowability of this application.

Respectfully submitted,

DANN DORFMAN HERRELL & SKILLMAN

A Professional Corporation

Attorneys for Applicant

Donald R. Piper, Jr.

PTO Registration No. 29,337

Telephone: (215) 563-4100

Facsimile: (215) 563-4044

-15-